K122455

APR 11 2013

Attachment A - Updated 510(k) Summary

Date Prepared: March 4, 2013

Sponsor:	Synthes Angela F. Lassandro 1301 Goshen Parkway West Chester, PA 19380 (610) 719-6854
Device Name:	Synthes Small and Large External Fixation Systems – MR Conditional
Classification:	Classification: Class II, §888.3030, Single/multiple component metallic bone fixation appliances and accessories. Product Code: KTT
Predicate Device:	Synthes Small External Fixation System (K031724, K033158, K961350, K031724, K050631, K090658, K082650, K952296, K040701) Synthes Large External Fixation System (K082650, K033158, K030390, K031428, K962913, K952296, K950384, K043039, K914558)
Device Description:	Synthes Reprocessed External Fixation Devices consist of various clamps, rods, bars and rings which are used to construct an external fixation frames in the treatment of various types of fractures.
Intended Use:	Synthes External Fixation Devices are intended for use in the construction of an external fixation frame for treatment of various fracture types that require external fixation.
Indications for Use:	The Synthes Small External Fixation System is intended to stabilize and provide treatment for fractures of the small bones, such as the hand, wrist, forearm, foot, and ankle. Specifically, the components can be used for: • Preliminary fixation before ORIF • Unstable fractures of the distal radius (both intra- and extra-articular) • Open and/or comminuted bilateral fractures • Fractures in combination with extensive soft tissue injury, bone loss, and vascular and/or neural involvement • Fracture dislocations • Failed closed reduction with casting resulting in secondary deformity (radial shortening and angulations) • Pediatric open fractures with bone loss and osteotomies

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	The Synthes Large External Fixation Systems is intended to provide treatment for long bone and pelvic fractures that require external fixation. Specifically, the components can be used for: • Stabilization of soft tissues and fractures • Poyltrauma/multiple orthopedic trauma • Vertically stable pelvic fractures, or as a treatment adjunct for vertically unstable pelvic fractures • Arthrodeses and osteotomies with soft tissue problems; failures of total joints • Neutralization of fractures stabilized with limited internal fixation • Non-unions/septic non-unions • Intra-operative reductions/stabilization tool to assist with indirect reduction • Unilateral rectilinear bone segment transport or leg lengthening
Substantial Equivalence:	Performance testing has been completed to demonstrate the use of Synthes Small and Large External Fixation Systems in the MR environment. Displacement and torque testing has met the requirements in ASTM F2052 and ASTM F2213, respectively. The devices were shown to have acceptable heating when tested for RF Heating in accordance with ASTM F2182. Image artifact for the devices was determined through testing in accordance with ASTM F2119. Additionally, an engineering analysis was conducted to assess mechanical strength of the Bridging Rod Component of the Synthes Large External Fixation System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Synthes
% Angela Lassandro
Regulatory Affairs Manager
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Letter dated: April 11, 2013

Re: K122455
Trade/Device Name: Synthes Small External Fixation System – MR Conditional, Synthes Large External Fixation System – MR Conditional
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliance and Accessories
Regulatory Class: Class II
Product Code: KTT
Dated: March 4, 2013
Received: March 5, 2013

Dear Ms. Lassandro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122455

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- Failed closed reduction with casting resulting in secondary deformity (radial shortening and angulations)
- Pediatric open fractures with bone loss and osteotomies

Prescription Use ____X____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael C. Owens

Division of Orthopaedic Devices

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